Remarks by Congressman Henry A. Waxman
CBI's Conference on Medicaid Rebates
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I'm pleased to join you here today at this conference on the Medicaid drug rebate program.

As someone who was deeply involved when the rebate program was first developed and passed into law, and as someone who still spends a lot of my time in Congress dealing with issues of drug prices and drug coverage, it is a timely and appropriate opportunity to share a few thoughts about where we've been and where we are going, what we've accomplished and what remains to be done.

But the first thing I want to do is to step back for a second and recognize what this program has actually done, because it's pretty impressive. The data we have show that between its start in 1991 and the year 2000, it was the source of nearly $20 billion dollars that were returned to the Federal government and the States in the form of rebate amounts.

That's a particularly significant figure when you put it in the context of a Medicaid program that is a critical source of health care for some 47 million people, and which is constantly struggling for sufficient funds to support these services.

We've got a rebate program in which about 500 manufacturers participate, that covers some 56,000 drugs, and where the rebates average approximately 17% .

The Enactment of the Medicaid Rebate Program:

So let's talk a little bit about how we got here.

I noticed in the brochure setting out your agenda the remark that although we've had the Medicaid drug rebate program for some 10 years, "the how and why the program was developed may still be a mystery to some."

Well, for those of us who were there, there's not much mystery.

Several very basic factors were in play.

First, there was an over-all budget summit going on, and out of that summit came specific instructions to the committees of jurisdiction to save nearly $2 billion in Medicaid over five years. And specifically, we were instructed to look at payments for Medicaid prescription drugs as a way to do it.

Second, probably very much as a result of the work of Senator Pryor, we were keenly aware that although the Medicaid program was a large purchaser of prescription drugs, it was not getting good prices for what it was buying. It seemed obvious that its purchasing clout ought to result in the program getting just as good a price as any other big buyer. Put simply, why should any buyer be getting a better price than Medicaid?

And finally, we also were aware that some State Medicaid programs ran formularies that were so restrictive that manufacturers could not get all their drugs covered and, more to the point, Medicaid beneficiaries were in some cases being denied access to drugs that they needed.

So out of the interaction of these factors came the making of a deal: a legislative policy that could benefit the States, the beneficiaries and the companies simultaneously, by giving something they wanted to all of them, but getting something back as well, and it could be accomplished because of the ultimate pressure of the reconciliation instructions which forced through action to save substantial dollars.

Initially, the focus was on a rebate that would in effect give the Medicaid program the best price being charged by the company to other buyers, and indeed that concept remained a critical part of the program. But as we worked on the legislation, it was obvious that some companies–Merck in particular–did not engage in reducing its prices for any buyer. So the concept of the alternate minimum rebate was added to the bill.

We recognized at the time that the Average Wholesale Price (or AWP) was subject to manipulation, and so we adopted the Average Manufacturer's Price (the AMP) as the base off which the discount would occur.

And, in what has clearly turned out to be a critical component of the bill, we recognized that we needed to protect against artificial inflation of the AMP once the program was operational. That was why we established what was in effect an inflationary limit on how much the AMP could increase. We did that by recouping in the rebate any increase beyond the inflationary amount.

Finally, in an agreement brokered with the industry, we established confidentiality protections for the AMP data. Access was limited to the Controller General and a very limited number of people in what was then HCFA. That also has turned out to be a critical decision, and one that perhaps in hindsight was not for the best. More on that later.

In any case, we ended up with the Medicaid drug rebate program. Although it hasn't been perfect, it has proved to be a very effective way to impact the prices Medicaid pays for its drugs.

More recent developments:

Price Effect:

Almost immediately after the program became effective, there were reports that the best price offered to other buyers was affected by the rule that extended it to the Medicaid program. While reports of the effect were clearly exaggerated, there is no doubt that some effect occurred.

Certainly it was felt by the Veterans' Administration, and we reacted in 1992 by exempting them from the best price calculation. At the same time, we extended the exemption to a limited number of other entities–PHS funded programs and State-run non-Medicaid pharmacy assisted programs, among them.

Currently there is some attention to extending the exemption to outpatient drugs purchased by public hospitals, a proposal that I have some sympathy with.

But I note the price effect on other payers not so much for the specifics of what happened with Medicaid itself, but as a warning lesson of some of the effects we need to consider as we move forward with a Medicare drug benefit.

Evasions of the best price rule:

In terms of the operation of the rebate program itself, recently there have been allegations that some companies were evading the requirements of the law, particularly relating to their reporting of prices.

My staff at the House Government Reform Committee began investigating these potential evasions of the Medicaid best price provision in 1999.

We received allegations that manufacturers were undermining the best price provisions through a repackaging scheme that was costing the Medicaid program millions of dollars.

- Here's how it worked....

- Manufacturers of popular drugs would sell these drugs to wholesalers. These wholesalers would then repackage and resell the drugs, with a new NDC code, to other large purchasers -- such as HMOs -- at extremely low prices.

- The drugs with the new NDC numbers were sold at prices below the Medicaid best price for the drug.

- But only the drug with the original NDC was sold to Medicaid beneficiaries. The manufacturers would then claim that the low prices on the repackaged drug were not related to the Medicaid best price on the original drug.

In 1999 we began to uncover circumstantial evidence that this type of repackaging scheme was occurring. For example, the number of drug repackagers, and the number of repackaged drugs were both increasing rapidly.

So we asked the HHS Inspector General to investigate. The results indicated that manufacturers were gaming the system.

- HHS found that manufacturers were avoiding paying the full rebate on drugs sold to and repackaged by three different HMOs. This was a clear violation of the law, which states that sales to HMOs must be included in best price computations.

- The IG reported that drugs were sold to HMOs at prices up to 75% below the reported best price. As a result, the Medicaid rebate program lost more than $100 million in 1998 - 1999.

- Following the release of the IG report, HHS clarified their guidance that this repackaging scheme was illegal, and began efforts to reclaim the lost funds.

At the same time that the information on the Medicaid repackaging scheme became public, it also became clear, through the work of the GAO and other investigative agencies, that some drug manufacturers were also taking undue advantage of the Medicare program.

These manufacturers were running what amounted to an Average Wholesale Price scam in order to give doctors extra incentives to prescribe their drugs.

- Manufacturers were marking up the published AWP, which was the basis for Medicare repayments, while charging doctors lower prices for the drugs.

- This increased costs for patients and the Medicare program, but increased profits for doctors each time they prescribed the drug. This was costing the Medicare program billions of dollars.

These two sets of abuses seem to indicate that given the opportunity, certain manufacturers will continue to try to evade the best price provisions.

That's why I asked the General Accounting Office to begin a broader investigation of the whether manufacturers have been evading Medicaid best price provisions, and if so, what mechanisms they were using to do so.

I was concerned when one of the drug manufacturers included in the investigation, refused to turn over important documents to GAO. Ultimately, they complied, although only after a subpoena threat. I believe this kind of behavior --- and the extreme efforts by drug manufacturers to maintain pricing secrecy at all costs -- only leads to suspicion that drug manufacturers have something to hide.

The GAO report has not yet been released, so I cannot discuss the findings. But I can tell you that if GAO finds further evidence that drug manufacturers have been gaming the Medicaid system, we will rapidly take action to recover lost funds and to fix the law so that these abuses cannot happen again.

There's another way we can get at these abuses: whistle blowers.

Obviously, in the Bayer and TAP Pharmaceutical cases brought under the False Claims Act that led to the corporate integrity agreements negotiated by the Inspector General (OIG), we were alerted to the practice by tips from whistle-blowers. The American public owes them a debt of gratitude. Not only did they uncover a practice that was evading the Medicaid law, but they alerted us as well to the problem in Medicare.

Obviously, the behavior that led to these cases is totally unacceptable. If it continues, more and more companies will find themselves negotiating stringent agreements with the OIG, with the accompanying oversight and penalties.

HHS and the OIG will address the Medicaid evasions, and Congress, I am confident, will act to close this loophole in the Medicare law.

Additional State rebate agreements:

Another development which has picked up considerable steam over the last year has been the efforts by States to negotiate additional rebates from manufacturers.

The tools used by the States typically reflect the kind of management tools we see used by private PBMs. Manufacturers that won't agree to additional rebates find their drugs subject to prior authorization and other utilization control requirements that reduce use of their products.

While we need to watch these programs carefully to be sure the basic requirements of access to drugs are not undermined for Medicaid beneficiaries, on the whole I think the more aggressive negotiations with pharmaceutical manufacturers are a commendable way for States to deal with the shortfalls in their Medicaid budgets.

I would note, however, that while large States with big markets may have considerable negotiating power with the companies, some of the smaller states may not.

That says to me that Congress would be well advised to examine an increase in the rebate amounts established under Federal law. That would use the maximum leverage of Medicaid to benefit all of the States.

Transparency

I would note that for all the advantages the rebate program brings to Medicaid, there is one area where not all the benefits have been realized. This is the area of setting appropriate reimbursement levels at the point where the drug is purchased.

The agreement that has kept the best price data and the AMP confidential has meant that States do not have the benefit of this information when they decide on their reimbursement amounts at the point of sale.

In the absence of the AMP data, States usually rely on some variation of AWP (average wholesale price) minus some percent. This puts State Medicaid programs in the same vulnerable position, and victim of the same kind of abuses, that have occurred in Medicare when the AWP is the basis for payment. It is a figure that can be easily manipulated.

To me these problems argue for at least a reconsideration of the issue of making the AMP transparent and available.

Prescription Drug Prices:

Over the past several years, both in the public and private sector, there has been increasing concern about the high price of prescription drugs.

Certainly, Members of Congress have shown a considerable and continued interest in the pricing of prescription drugs, particularly drug prices for seniors, both because of the need to add a prescription drug benefit to Medicare and because of the evidence of discriminatory prices faced by many seniors who currently are without third party drug coverage.

- Much of the interest has been sparked by investigations by my staff on the House Committee on Government Reform that have documented rampant discrimination in prescription drug pricing.

- In the last four years, the minority staff of the Committee has written over 250 reports for over 100 Members of Congress on pricing issues.

- These reports have consistently found that drug manufacturers engage in pervasive price discrimination, charging consumers without market power more than they charge other customers.

- And uninsured seniors are the ones paying the highest prices.

The reports have identified a number of examples of the problem.

- For example, the reports have found that uninsured U.S. seniors can pay several times what consumers in other countries pay for identical drugs. Prilosec, was the best selling drug for seniors in 2000. The average price for uninsured seniors in the U.S. is over twice as high as the average price in Canada, Europe, and Japan.

- Two years ago Republicans in Congress passed prescription drug import legislation that they claimed would solve this problem by allowing wholesalers to import drugs from other countries. But this law was so full of special-interest loopholes that both the Clinton and Bush administrations determined that it was not even worth implementing.

- The minority staff reports have also investigated the prices paid by favored domestic customers, such as HMOs, PBMs, and the federal government. The findings were similar -- uninsured seniors are lacking in market power, and as a result, they pay significantly higher prices than favored customers.

- The committee staff has even investigated the pricing of drugs for animals. They found that drug manufacturers charge twice as much for drugs when they are used to treat humans than they charge when the identical drugs are used to treat animals. For example, the arthritis drug Lodine is used to treat both arthritic seniors and arthritic dogs. But it costs almost three times as much when it is purchased to treat ill seniors.

- My staff has also conducted other studies on drug pricing and drug coverage. They have specifically analyzed breast cancer drugs, and found that there is extensive manufacturer price discrimination for this class of drugs. And they have done a number of reports highlighting the number of uninsured seniors in individual states.

These reports touch a nerve with members because of the unfairness of the situation. It is simply not right that the group with the greatest need for prescription drugs and the least ability to pay is being charged the highest prices.

My staff is going to continue to investigate prescription drug pricing and prescription drug price discrimination, and I know that these investigations will continue to garner interest from the media, from constituents, and from legislators.

Ultimately, the abuses highlighted in these reports will need to be fixed. And we know that many of them will disappear if we provide seniors with a strong and meaningful drug benefit in Medicare.

Medicare Drug Benefit

Finally, even though I know it's not the subject of your conference, let me say a few words about Medicare.

Only a few days ago, I worried I would miss this event because the Commerce Committee would be in the middle of an anticipated mark-up on prescription drug legislation.

Obviously that time table has slipped.

The design of a good and comprehensive drug benefit is not easy, particularly it is not easy to pay for. That's a problem that faces both parties.

I am convinced not only that we can do it, but that we must do it. The day is long past when we can consider prescription drugs as anything other an integral part of medical care.

Further, I firmly believe drugs should be treated like any other Medicare benefit, with the same coverage, the same cost sharing, and the same availability throughout the program. No one should have to enroll in a medicare+choice plan to get drug coverage; no one should have to buy a supplemental private policy to get it.

Sure, it will be expensive. But we have the resources available: now we must establish that this is our priority.

It seems clear in the House that the majority party intends to develop their proposal behind closed doors and spring it on members without hearings or time for consideration or amendment. That is to me a really reprehensible way to move forward on the most major change in Medicare since its inception.

To return to the specific interests you all have here, however, let me just note this. It is my belief that whatever we do in Medicare, for the foreseeable future we will have Medicaid drug coverage, and I believe the Medicaid rebate system will stay in effect.

We all of us will need to do some detailed work on how the programs will mesh. In some sense, much of that work remains to be done when we see more clearly the ultimate design the Medicare benefit will take.

In the meantime, the rebate system is here, it is in place, and it makes an important contribution to the affordability of the Medicaid drug benefit.

Compliance with the requirements of the law remain the obligation of each of you in this room.

Thank you for the opportunity to join you here today.